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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,359	07/11/2001	Ulrich Laemmli	62574-A/JPW/GJG	9566

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Gary J. Gershik
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
ZITOMER, STEPHANIE W	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/903,359	Applicant(s) LAEMMLI et al.
	Examiner S. Zitomer	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 30, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5, 51-57, 69-72, 79-82, and 85* is/are pending in the application.

4a) Of the above, claim(s) *85* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-5, 51-57, 69-72, and 79-82* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Restriction and election

1. The restriction set forth in paper no. 12 mailed September 26, 2002 has been withdrawn. Therefore, applicant's election in paper no.13 filed October 30, 2002 is moot.

Informalities

2. The disclosure is objected to because of the following informalities:

(a) The continuing information paragraph at page 1 of the specification is incomplete in missing the status of the CIP parent application.

(b) Page 34 has four lines of text at the top and the rest of the page is blank. If the application goes to issue this will confuse the printer as it is unclear whether text is missing or the blank is intentional and serves a purpose.

Appropriate correction is required.

References in specification

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Nonstatutory claim

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 85 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Accordingly, claim 85 has been withdrawn from consideration.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 70 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 70 is drawn to a process for "chromatin remodeling of the CRE" by the DNA binding molecule of claim 1 wherein the "chromatin remodeling...alters the activity of one or more other DNA elements, so-called "modulated DNA elements" in the genome". The specification at page 27 provides the basis for this claim but it does not define the "CRE" as to its location or nucleotide sequence and does not teach alteration of "the activity of one or more other DNA elements". Example 6 at pages 49-51 describes chromatin remodeling and sequence-specific topoisomerase II cleavage mediated by oligopyrroles whereas the "chromatin response element" is not mentioned nor are the recited other "DNA elements" identified or mentioned. In addition to enablement the first paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. It appears that applicant was in possession of a "chromatin remodeling" process as described in Example 6 but the specification does not support "remodeling of the CRE alters the activity of one or more other DNA elements" as recited in claim 7.

Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 51-57, 69-72, 79-82 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims are confusing due to the recitation "capable of" in claim 1 and "having the capacity to" in claim 70 because it is unclear whether a process or a property is intended. It is suggested to use direct language for clarity, e.g., replace "capable of...binding" and "having the capacity to bind" with --binds--.

(b) In claim 4, if "derivatives of any of these compounds" is to be included in the Markush group, "or" in line 4 should be --and--. The "or" indicates that "residues" and "derivatives" are separate groups from which to choose, i.e., they may not be mixed.

(c) Claim 4 is indefinite because "derivatives" is an indeterminate term which is not defined in the claim or in the specification. For example, its possible meanings range from a single atom of a recited heterocyclic residue to a very large multimer molecule to which a heterocyclic residue is attached. It is noted that "substituent which is DNA-binding or non-DNA-binding" is not definitive.

(d) Claim 5 is confusing in the use of "and/or" in the Markush group. See above at (b). It is suggested to delete "or" at both occurrences.

(e) In claim 70 the phrase "so-called" renders the claim indefinite because it is unclear as to whether the "CRE" is a response element or something else by another name. It is suggested to delete "so-called" as it is clear from the specification

(f) Claim 71 is indefinite in depending from canceled claims.

(g) Claims 70-72 and 79-82 lack antecedent basis in claim 1 for "said compound" because claim does not recite "compound" and the intended antecedent cannot be determined.

(h) In claim 82 the phrase "such as" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "such as"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Rejection under 35 U.S.C. 102(b): Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 51-57, 70-82 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/37066. The claim 1 minor groove DNA binding molecule characterized in that it comprises at least two sequence specific DNA binding elements covalently linked to each other in tandem orientation by an amphipathic, flexible linker molecule at least one of which is non-proteinaceous is disclosed at page 55, claims 13-14 and page 17, lines 1-4. The embodiment of claim 2 wherein at least one of the DNA binding elements comprises an oligomer comprising one or more organic heterocyclic amino acid residues is disclosed at page 2, lines 13-15 identifying imidazole and pyrrole heterocyclic residues. The embodiment of claim 3 wherein each organic heterocyclic residue of claim 2 has at least one annular nitrogen, sulphur or oxygen is disclosed at page 2, lines 13-15 identifying imidazole and pyrrole heterocyclic residues and other residues which have annular nitrogens. The embodiment of claim 4 wherein the heterocyclic residue of claim 2 is chosen from the group comprising pyrrole and imidazole and derivatives thereof is disclosed at page 10, lines 10-16 as pyrrole and imidazole. The embodiment of claim 5 wherein in at least one oligomer of claim 4 includes heterocyclic residues chosen from a group comprising 3-hydroxy-N-methylpyrrole and others is disclosed at page 10, lines 11-12 as 3-hydroxy-N-methylpyrrole.

The claim 51 process for binding double-stranded DNA in a sequence-specific manner comprising contacting a DNA target sequence with a DNA binding molecule of claim 1 in conditions allowing binding to occur is disclosed at page 33, Example 7. The embodiments of claims 52-54, 56 and 57 wherein the process is carried out *in vivo* in a cell which is a eukaryotic, vertebrate, mammalian cell is disclosed at page 6, lines 9-30.

The embodiments of claims 71-72 wherein the claims are drawn to a cell containing a "compound" of claim 1, interpreted as the DNA binding molecule of claim 1, and wherein the compound binds the DNA minor groove are disclosed at page 6, lines 9-11.

The embodiment of claim 79 wherein the "compound" of claim 1 is in a pharmaceutical composition with a physiologically acceptable excipient and the embodiment

of claim 80 wherein the claim "compound" is "for therapy" is disclosed at page 7, lines 4-11.

The embodiments of claims 81 and 82 wherein the "compound" is fluorescently labeled and the label is fluorescein are disclosed at page 8, line 2.

Rejection under 35 U.S.C. 102(e): Anticipation

8. Claims 1-5, 51-57, 71, 72 and 79-82 are rejected under 35 U.S.C. 102(e) as being anticipated by the patent to Dervan et al. (5,998,140). The claim 1 minor groove DNA binding molecule characterized in that it comprises at least two sequence specific DNA binding elements covalently linked to each other in tandem orientation by an amphipathic, flexible linker molecule, column 30, claim 1 with column 5, lines 44-49 which identifies the amphipathic, flexible linker molecule as β-alanine and at column 31, claim 3. The embodiment of claim 2 wherein at least one of the DNA binding elements comprises an oligomer comprising one or more organic heterocyclic amino acid residues is disclosed at column 31, claim 3. The embodiment of claim 3 wherein each organic heterocyclic residue of claim 2 has at least one annular nitrogen, sulphur or oxygen is disclosed at column 31, claim 3 identifying imidazole and pyrrole heterocyclic residues and other residues which have annular nitrogens. The embodiment of claim 4 wherein the heterocyclic residue of claim 2 is chosen from the group comprising pyrrole and imidazole and derivatives thereof is disclosed at column 31, claim 3 as pyrrole and imidazole. The embodiment of claim 5 wherein in at least one oligomer of claim 4 includes heterocyclic residues chosen from a group comprising N-methylpyrrole and others is disclosed at column 4, lines 60-63 as N-methylpyrrole.

The claim 51 process for binding double-stranded DNA in a sequence-specific manner comprising contacting a DNA target sequence with a DNA binding molecule at column 33, claim 22 and column 34, claim 28. The embodiments of claims 52-57 wherein the process is carried out *in vivo* in a cell which is a eukaryotic or invertebrate or mammalian cell or a prokaryotic cell is disclosed at column 15, line 56-column 16, line 5..

The embodiments of claims 71-72 wherein the claims are drawn to a cell containing a "compound" of claim 1, interpreted as the DNA binding molecule of claim 1, and wherein

the compound binds the DNA minor groove are disclosed at column 30, claim 1 and column 31, claim 3.

The embodiment of claim 79 wherein the "compound" of claim 1 is in a pharmaceutical composition with a physiologically acceptable excipient and the embodiment of claim 80 wherein the claim "compound" is "for therapy" are disclosed at column 15, line 66-column 16, line 63.

The embodiments of claims 81 and 82 wherein the "compound" is fluorescently labeled and the label is fluorescein are disclosed at column 7, lines 24-30.

Conclusion

9. **No claim is allowed.** However, claims 69 and 70 would be allowable if the rejections under 35 U.S.C. 112 were overcome.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact LIE Chantae Dessau at 703-605-1237.

S. Zitomer

Stephanie Zitomer, Ph.D.

January 7, 2003

STEPHANIE W. ZITOMER
PRIMARY EXAMINER